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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/647,599

10/03/2000

Leigh T Canham

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7590

06/23/2005

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 163-166 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 163-166 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment dated 4-17-05 is acknowledged.

Claims included are 163-166.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 163-166 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation 'elemental sulfur' now added in claims 163 and 164 has no support in the specification as originally filed and therefore, deemed to be new matter. The locations in the specification and the figure 5 have no support for this specific element. Fig. 5 for example is the periodic table.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 163-167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is unclear as to what applicant intends to convey by 'beneficial substance comprising elemental sulfur' in claim 163. Is the beneficial agent 'sulfur' as such or a compound where in sulfur is present as sulfide or other forms? There is no specific definition in the specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 163-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/06101 of record in combination with Cortese (4,608,048), Gopferich (WO 97/32570, English Equivalent, US 6,086,908).

7. WO discloses biomaterial wherein the bioactive porous silicon is impregnated with active agents such as calcium, sodium or phosphorous. The implant device may be a sensor device or a device for intelligent drug delivery (abstract, page 6, lines 5-6). According to WO, bioactive silicon provides the advantage over other bioactive materials in that it is compatible with silicon based integrated circuit technology (page 3, lines 1-2). The porosity is taught on page 13, lines 10-29. Although the porous silicon impregnated with calcium, sodium or phosphorous used in the examples, WO on page

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3, lines 23-29 teaches that bioactive silicon could be either microporous (pore diameter 20 Å) or mesoporous (pore diameter 20 Å to 500 Å). Although the implant in WO has two specific regions of silicon, the porous region and the bulk region, WO does not specifically teach that the implant could be used for sequential delivery of drugs.

Cortese (4,608,048) while disclosing a drug delivery device containing microporous material teaches that the device can be used to deliver two drugs sequentially (abstract, col. 2, lines 21-35, col. 7, line 47 through col. 8, line 18). Cortese does not teach silicon as the microporous material.

Gopferich while disclosing a sequential drug release device teaches that if the same active compound is administered continuously, tumor cells tend to develop resistances and that implants which release pharmaceutical substances discontinuously or sequentially could counteract this development (col. 1, lines 14-33 of the English equivalent, 6,086,908).

To load a single drug or different drugs in different bioerodable regions of the implant of WO would have been obvious to one of ordinary skill in the art since the references of Cortese, and Gopferich show the routine use in the art and that of Gopferich in particular teaches the advantages of using sequential or discontinuous delivery of a single drug or different drugs.

Alternately, to use bioactive silicon as the porous material in Cortese or Gopferich would have been obvious to one of ordinary skill in the art because of the advantages of silicon over other bioactive material taught by WO 97/06101.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Cortese mentions silicone, which is an organic polymer and not elemental silicon. This argument is not found to be persuasive since Cortese is combined for its teachings of the use of microporous materials for sequential delivery of drugs. Applicant's arguments that since none of the references disclose the use of elemental sulfur, such a combination of references does not result in the new claim 163 invention. This argument is not found to be persuasive since WO teaches generic 'drug' delivery' and teaches also impregnation of calcium, sodium and phosphorous and therefore, it would have been obvious to one of ordinary skill in the art to use any drug including sulfur. Furthermore, claims are given the broadest reasonable interpretation and as acknowledged by applicant himself, Cortese does teach a number of compounds containing sulfur. These beneficial substances comprise elemental sulfur, as instant claim 163 requires. Applicant's arguments that electronic intelligent drug delivery is the only of drug delivery mentioned by WO 101 and therefore, this would lead the skilled person away from the use of a barrier to sequentially release a beneficial substance are not persuasive since 1) instant claim language does not exclude the use of electronic way of delivering the drugs; 2) instant claims do not define what the barrier is and WO teaches porous silicon wherein the beneficial agents are impregnated and therefore, silicon is a barrier as in instant invention; 3) WO in fact states 'bioactivity of the bioactive silicon *maybe* controlled by the application of an electrical potential (abstract) which implies that electronic way is not the only way as argued by applicant. The rejection is maintained.

8. Claims 163-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/06101 of record in combination with Cortese (4,608,048), Gopferich (WO 97/32570, English Equivalent, US 6,086,908), further in view of Asato (4,036,979).

The teachings of WO, Cortese and Gopferich have been discussed above. What is lacking in their teachings is the use of elemental sulfur as the beneficial agent. However, one of ordinary skill in the art would be motivated to use elemental sulfur as the beneficial agent with a reasonable expectation of success since the reference of Asato shows the routine use of elemental sulfur in growth promoting compositions for homothermic animals (abstract and Table on col. 8).


9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK